

We are conducting a new clinical research study that may be of interest to you! The **B-SUPREME phase 2 study** will assess the safety and effectiveness of an investigational* medicine called ALG-000184 in people with clinical diagnosis of chronic hepatitis B virus (HBV) infection:

- HBV infection is a worldwide public health problem that affects 296 million people globally, and an estimated 1.1 million deaths per year are caused by HBV-related diseases (e.g., liver cancer, liver cirrhosis). Advanced liver disease occurs in 20%–30% of chronically HBV-infected adults.
- You may be eligible to take part in this study if you**



Are between 18–65 years of age with a diagnosis of chronic HBV infection or chronic hepatitis B***



Have either: never received HBV treatment, or have not received HBV treatment within the last 6 months before enrolling in the study



Have never received a capsid assembly modulator (CAM) treatment

This brochure will provide you with information about clinical research in general, explain why we are conducting this study and describe what participation it involves.

*“Investigational” means the study medicine is approved for use in clinical research but not yet approved for the treatment of chronic HBV infection. It is not known if the study medicine will help you.

**Full eligibility criteria apply

*** (or minimum age by local regulatory requirements)



Learn more

If you decide to take part in the study, all study-related medicines and assessments will be provided to you at no cost. You may also be reimbursed for some expenses such as travel or transportation. Study staff can provide additional details regarding costs and reimbursement for this study.

Participation is voluntary and you would be able to leave the study at any point without penalty.

If you agree, your treating physician can be informed of the trial process and your progress, and will be equipped to support you should you decide to leave.

Thank you for your interest in the **B-SUPREME study!**

If you think you might be interested in this study or would like more information to see if you are eligible, please visit: b-supremestudy.com



DO YOU HAVE CHRONIC HEPATITIS B VIRUS INFECTION?

You may be eligible for the **B-SUPREME study**, a new phase 2 clinical research study, investigating a potential treatment for chronic hepatitis B virus infection.



What is a clinical research study?

Clinical studies evaluate new ways to prevent, detect or treat many conditions, including chronic HBV. They provide valuable information about the safety and effectiveness of potential new medications. All medications must be tested in clinical studies before they may be used for patients in the general public. Without them, no new treatments could be developed.

Clinical studies follow strict standards (rules) and are closely regulated. Every study is reviewed and monitored closely to make sure that the rights of participants are protected, no unnecessary risks are involved and that the study answers important medical questions.

What is the purpose of the B-SUPREME study?

Although the current standard of care treatment for chronic HBV infection has been well tolerated and suppresses activity of HBV DNA, the suppression is not complete and many people with chronic HBV infection still have detectable HBV DNA levels despite being on current standard of care treatment. Evidence shows that any level of HBV DNA can be related to adverse clinical outcomes, even at low HBV DNA levels and incomplete viral HBV DNA suppression. Because of this risk, there remains an unmet medical need to find more effective antiviral medicines to maximize HBV DNA suppression which may result in improved clinical outcome.

The B-SUPREME study has been designed to evaluate an investigational medicine called ALG-000184 which may reduce the HBV DNA levels in the blood. We're conducting this study to evaluate the effectiveness and daily oral doses of ALG-000184 compared with standard treatment, in patients with chronic HBV infection.

Previous clinical studies showed that taking ALG-000184 daily was safe for healthy people. The medicine was also safe for patients with chronic HBV infection and substantially reduced HBV DNA levels, when taken for up to 96 weeks.

What will happen during the study?

The B-SUPREME study will include approximately 194 adults with chronic hepatitis B or chronic HBV infection and will last approximately 112 weeks (28 months). If you are eligible and decide to enroll in this study, you will receive the study treatment, either ALG-000184 or placebo of tenofovir disoproxil fumarate (TDF, the standard of care), assigned at random (by chance) orally once daily for first 48 weeks, followed by additional 48 weeks of open-label extension dosing period of ALG-000184.

The Study is divided into the following stages:



SCREENING: Screening for the study can take up to 8 weeks, during this time study doctors will ask you several medical questions and you will have health tests to determine if you qualify for this study.



DOUBLE-BLIND DOSING PERIOD: You will be randomly assigned to one of two groups at the start of the treatment period and will take study treatment orally (by mouth) once daily for 48 weeks at approximately the same time every day.



OPEN-LABEL EXTENSION DOSING PERIOD: After finishing the first 48-week dosing period, you will be allowed to enter into a 48-week treatment extension period where you will receive ALG-000184. During this time, you will be required to visit the study center every 8 weeks until Week 84 and then every 6 weeks until Week 96.



FOLLOW-UP: At the end of the dose extension period (Week 96), you may have the option to enter a separate long-term follow-up (LTFU) study. This study will allow continuation of ALG-000184 monotherapy for up to 3 to 4 years to assess its long-term safety and efficacy. Alternatively, if you are not willing to be treated with ALG-000184 in the long-term, you will have one final visit at 8 weeks after your last dose of ALG-000184.

Patients will be receiving 300 mg ALG-000184 or placebo of tenofovir disoproxil fumarate (TDF, the standard of care) during the Double-Blind Dosing Period.

How would my health be monitored?

The health assessments will vary from visit to visit, but may include:



Physical examination



Blood and urine tests



12-lead electrocardiogram (ECG)



HIV and hepatitis tests



Vital signs



Liver ultrasound

Some of these assessments may be a little uncomfortable and/or carry certain risks but the study team will explain each assessment to you in detail if you decide to take part.

Are there any potential risks?

It's important to remember that, as with any treatment, you can never be sure of the outcome. Your health may improve, it may stay the same or it may get worse.

It's also possible that you may experience side effects related to the study treatment. If you experience any side effects related to participating in the study, you will be well taken care of by the study team.

The study team will be there to support you throughout participation, should any questions or issues arise.



There is no cost to participate in this study, all study-related medication, tests will be provided at no charge and reimbursement will be provided for travel/transportation